South Dakota Department of Health
Correctional Health Services

Hepatitis C Biopsy Eligibility Checklist

To be completed prior to referral for liver biopsy.

Offender Name: _____ **DOC #:** _____

Any answers outside the shaded box excludes the offender at this time. See * Notes below.

Questions 1-3 to be completed by Health Services Staff.

1. Age between 18 and 65.	Yes	No
2. Suggested Release Date more than 18 months from today's date.	Yes	No
3. Positive urine drug screen in the proceeding 6 months.	Yes	No

Questions 4-20 to be completed by Practitioner.

4. Liver enzyme elevation twice at 6 month intervals.	Yes	No
5. Hepatitis C RNA test positive (either qualitative or quantitative).	Yes	No
6. Free of Non-Hepatitis C liver disease.	Yes	No
7. Willing to consider treatment for Hepatitis C.	Yes	No
8. Willing to have liver biopsy.	Yes	No
9. Normal coagulation function (no evidence of bleeding or clotting disorder).	Yes	No
10. Allergy to Ribiviron or Interferon.	Yes	No
11. Evidence of decompensated liver disease such as ascites, bilirubin greater than 2.0, albumin less than 3.0, or history of visceral bleeding.	Yes	No
12. Approval from psychiatrist.	Yes	No
13. Clinical evidence of uncontrolled thyroid Disease.	Yes	No
14. Pregnant.	Yes	No
15. Significant cardiac arrhythmias or symptomatic cardiac disease functional Class II or greater.	Yes	No
16. Autoimmune disorder.	Yes	No
17. History of organ transplant.	Yes	No
18. Evidence of hemoglobinopathy.	Yes	No
19. Receiving dialysis.	Yes	No
20. Evidence of lung disease.	Yes	No

Describe other significant health problems:

Practitioner Signature/Title: _____ Date: _____

Notes:

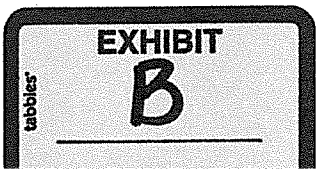
*Questions 1-2, 4-9, & 12 : "No" excludes from eligibility.

*Questions 3, 10-11, & 13-20: "Yes" excludes from eligibility.

*Question 3: Drug testing not necessary, but if one was done and positive with in the past 6 months, the offender is excluded.

*Questions 7-19: Laboratory test are not required unless clinical findings or history suggest that they are necessary to document or exclude a conditions.

11/13/02



South Dakota Department of Health
Correctional Health Services
Consent for Hepatitis C Evaluation and Treatment

Offender Name	DOC Number	Facility

1) I understand that I have Hepatitis C infection and that blood tests have suggested that there is active disease in my liver. I understand that most people with Hepatitis C infection do not develop significant liver disease even after 20 or more years of infection: Between 5% and 20% of people with Hepatitis C get serious progressive liver disease. I also understand that treatment for Hepatitis C can cause many serious side effects and make certain medical conditions worse: it can even lead to death in some cases. I understand that the policy of the Department of Health is to offer treatment only if I have progressive permanent liver disease present on liver biopsy, when my remaining time to be served is greater than the usual treatment and follow-up period (usually 18 months), if I am drug and alcohol free as determined by random testing during the period before and during treatment, after I have satisfactorily completed Chemical Dependency treatment if I am chemically dependant, and if I do not have any medical conditions (including recent or serious mental illnesses) that is a contraindication to treatment. I also understand that if I have a history of poor cooperation with medical, psychiatric, or mental health treatment or evaluation, treatment may be deferred until I show that I will cooperate with these procedures.

2) I agree to proceed with further evaluation of my liver with a liver biopsy and further blood test. I understand that there are certain risks associated with the liver biopsy that include possible allergic reaction to the local anesthetic used to numb my skin, pain at the area were the needle is inserted, possible severe bleeding, and possible injury to my gallbladder or other internal organs. I understand that complications of liver biopsy and be life threatening. I understand that the biopsy will be performed by personnel trained in this procedure, that the biopsy will be performed only if I have normal clotting and no fluid accumulation in my abdominal cavity (ascites), and that I will be observed for the rest of that day and the next.

3) I understand that if I have significant active damage and scar tissue formation (fibrosis) revealed by my liver biopsy, I might be a candidate for receiving Interferon and Ribavirin treatment. I understand that the biopsy might show only small amount of damage or ever severe liver disease (cirrhosis), in which case I would not be offered Interferon and Ribavirin therapy.

4) I understand that there are many side effects of receiving Interferon and Ribavirin. Interferon will be injected under my skin three (3) times a week or weekly and can cause fatigue, aching, headache, loss of appetite, weight loss, difficulty sleeping, anxiety, irritability, and depression which could be so severe that I might commit suicide. Interferon can also lower my white blood cells and platelets, causing thyroid problems, heart problems, and worsening of liver disease. Ribavirin pill must be taken two (2) times a day and this medication can cause breakdown of my red blood cells with a resulting anemia. It can also cause skin rash, itching, shortness of breath, cough, sore throat, nasal congestion, stomach pain, and loss of appetite. These side effects of Interferon and Ribavirin can be severe and cause death. I understand that I will need to make frequent visits to Health Services to have blood tests and that the Interferon and Ribavirin doses may have to be adjusted or discontinued. I understand that if I fail to cooperate with medical follow-up, psychiatric or psychological follow-up, or laboratory testing, treatment will be discontinued.

5) I understand that no promises or guarantees have been made to me that I will receive the Interferon and Ribavirin after the biopsy. I also understand that if I don receive these medications, the treatment may not eliminate the Hepatitis C virus or prevent cirrhosis of the liver or prevent development of liver cancer.

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6) I understand that if I have a history of drug and alcohol abuse, I must satisfactorily complete a substance abuse program prior to liver biopsy of Hepatitis C treatment. I understand that I will be randomly tested for illegal drugs and alcohol prior to and during Hepatitis treatment. If I test positive or if I refuse the tests, therapy will be stopped.

7) I understand that Ribavirin causes birth defects. If I am a woman, I must not become pregnant while on Ribavirin and for six (6) months after I stop taking it. If I am a man, I must not make a woman pregnant during the time I am on Ribavirin and for six (6) months after I stop taking it.

8) I understand the after treatment is started, tests will be done to monitor the effectiveness and side effects of treatment and that treatment may be stopped if determined to be ineffective rot for significant side effects. The test to determine treatment effectiveness is the viral load which goes to undetectable levels if treatment if effective.

9) I have discussed with my doctor the following risk or issues in addition to those mentioned above concerning my medical condition and the evaluation and treatment of my Hepatitis C:

_____

_____

_____

_____

10) I have discussed with my doctor the risks/benefits of having a liver biopsy and receiving Interferon and Ribavirin. All of my questions have been answered in term and language that I understand.

11) I understand that I ma withdraw my consent for liver biopsy, testing, and treatment at any time. If I do not consent at this time, I can change my mind and be considered for evaluation and treatment in the future.

	I agree to have further evaluation of my Hepatitis C with liver biopsy, more laboratory studies, and psychological and medical follow-up. If indicated, I agree to receive Interferon and Ribavirin for treatment of my Hepatitis C.
	I decline further evaluations of my Hepatitis C and do not with to have a liver biopsy, and understand that I will not receive Interferon and Ribavirin therapy.

Offender Signature:	Date:
Physician Signature:	Date:

Pegasys Therapy Personal Laboratory Summary Sheet

Patient Name: _____	Therapy Start Date:	Target End Date:
Physician Name: _____	Therapy: Pegasys Dose: _____ µg weekly on _____	
RN Name: _____	Copegus Dose: _____tablets QAM _____Tablets QPM	

	Baseline	Week 1	Week 2	Week 4	Week 6	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 60	Week 72
Date																		
WBC																		
HGB																		
HCT																		
PLATELET																		
INR																		
NEUTROPHIL																		
ALBUMIN																		
TOTAL BILI																		
ALT																		
AST																		
TSH																		
HCV Viral Load																		
Pregnancy test																		
Other																		

Comments: _____

_____

_____

This form is only intended to supplement your monitoring efforts. It should not be used to decide which test to perform for an individual patient.

Date Started: 9/9/2010

Week 1 9/16/2010	**Week 2** 9/23/2010	**Week 3** 9/30/2010	**Week 4** 10/7/2010
Week 5 10/14/2010	**Week 6** 10/21/2010	**Week 7** 10/28/2010	**Week 8** 11/4/2010
Week 9 11/11/2010	**Week 10** 11/18/2010	**Week 11** 11/25/2010	**Week 12** 12/2/2010
Week 13 12/9/2010	**Week 14** 12/16/2010	**Week 15** 12/23/2010	**Week 16** 12/30/2010
Week 17 1/6/2011	**Week 18** 1/13/2011	**Week 19** 1/20/2011	**Week 20** 1/27/2011
Week 21 2/3/2011	**Week 22** 2/10/2011	**Week 23** 2/17/2011	**Week 24** 2/24/2011
Week 25 3/3/2011	**Week 26** 3/10/2011	**Week 27** 3/17/2011	**Week 28** 3/24/2011
Week 29 3/31/2011	**Week 30** 4/7/2011	**Week 31** 4/14/2011	**Week 32** 4/21/2011
Week 33 4/28/2011	**Week 34** 5/5/2011	**Week 35** 5/12/2011	**Week 36** 5/19/2011
Week 37 5/26/2011	**Week 38** 6/2/2011	**Week 39** 6/9/2011	**Week 40** 6/16/2011
Week 41 6/23/2011	**Week 42** 6/30/2011	**Week 43** 7/7/2011	**Week 44** 7/14/2011
Week 45 7/21/2011	**Week 46** 7/28/2011	**Week 47** 8/4/2011	**Week 48** 8/11/2011